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## NOTICE OF ALLOWANCE AND FEE(S) DUE

22245 7590 02/11/2004

NAVAL MEDICAL RESEARCH CENTER  
ATTN: (CODE 00L)  
503 ROBERT GRANT AVENUE  
SILVER SPRING, MD 20910-7500

EXAMINER

SHANNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/11/2004

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/747,521      | 12/21/2000  | Darrel R. Galloway   | 22727/04079         | 9991             |

TITLE OF INVENTION: METHODS FOR PROTECTION AGAINST LETHAL INFECTION WITH BACILLUS ANTHRACIS

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE | PUBLICATION FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|-----------|-----------------|------------------|------------|
| nonprovisional | NO           | \$1330    | \$300           | \$1630           | 05/11/2004 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), to: **Mail**

**Mail Stop ISSUE FEE  
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or Fax (703) 746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

22245 7590 02/11/2004

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

|                    |
|--------------------|
| (Depositor's name) |
| (Signature)        |
| (Date)             |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER               | ART UNIT | CLASS-SUBCLASS |
|------------------------|----------|----------------|
| SHAHNAN SHAH, KHATOL S | 1645     | 424-190100     |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

|   |       |
|---|-------|
| 1 | _____ |
| 2 | _____ |
| 3 | _____ |

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

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| 09/747,521   | 12/21/2000  | Darrel R. Galloway   | 22727/04079            | 9991             |
| 22245  | 7590        | 02/11/2004           | EXAMINER               |                  |
| NAVAL MEDICAL RESEARCH CENTER<br>ATTN: (CODE 00L)<br>503 ROBERT GRANT AVENUE<br>SILVER SPRING, MD 20910-7500 |             |                      | SHAHNAN SHAH, KHATOL S |                  |
|  |             |                      | ART UNIT               | PAPER NUMBER     |
|  |             |                      | 1645                   |                  |

DATE MAILED: 02/11/2004

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

# Notice of Allowability

Application No.

09/747,521

Examiner

Khatol S Shahnan-Shah

Applicant(s)

GALLOWAY ET AL.

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1645

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview of 11/19/2003 and amendment of 12/18/2003.
2. ☒ The allowed claim(s) is/are 24, 26, 27, 31, 41, 42, 45-50 and 53 renumbered claims 1-13 respectively.
3. ☒ The drawings filed on 12 December 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____             |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input type="checkbox"/> Examiner's Amendment/Comment                             |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|  | 9 <input type="checkbox"/> Other  |

***Attachment to Notice of Allowance***

1. Applicants' amendment, received 18 December 2003, paper #26 is acknowledged. The amendment has been entered. Claims 24, 26, 27, 31, 41, 42, 45-50 and 53 have been amended. Claims 23, 51 and 52 have been canceled. Applicants' exhibits A, B and C as requested by this office on the interview of 11/18/2003 (paper #25) are acknowledged.
2. Claims 24, 26, 27, 31, 41, 42 and 45-50 and 53 are pending.

***Objections Withdrawn***

3. Objection to the specification made in paragraph 12 of the office action mailed 5/7/2003, paper #17 is withdrawn in view of applicants' corrections.
4. Objection to the specification made in paragraph 13 of the office action mailed 5/7/2003, paper #17 is withdrawn in view of applicants' arguments and corrections.

***Rejections Withdrawn***

5. Rejection of claims 23, 24, 26, 27, 31, 41 - 42 and 45-50 under 35 U.S.C. 112, first paragraph made in paragraph 14 of the office action mailed 5/7/2003, paper # 17 is withdrawn in view of applicants' amendments and exhibits.
6. Rejection of claims 23, 24, 26, 27, 31, 41 - 42 and 45-50 under 35 U.S.C. 112, first paragraph made in paragraph 15 of the office action mailed 5/7/2003, paper # 17 is withdrawn in view of applicants' amendments and exhibits.
7. Rejection of claims 23, 24, 26, 27, 31, 41, 42 and 45-50 under 35 U.S.C. 112, second paragraph made in paragraph 16 of the office action mailed 5/7/2003, paper # 17 is withdrawn in view of applicants' amendments.

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***Reason for Allowance***

8. Claims 24, 26, 27, 31, 41, 42, 45-50 and 53 are allowed. Claims are renumbered 1-13 respectively.

The following is an examiner's statement of reasons for allowance:

Claims are drawn to an immunogenic composition comprising

(a) a first polynucleotide that encodes a mutated *B. anthracis* lethal factor (LF) protein or a fragment thereof that encodes amino acid 42 to 285 of SEQ ID NO: 2, said first polynucleotide being operably linked to a promoter that drives expression of said LF protein or fragment thereof in cells of a mammalian subject, and

(b) a second polynucleotide which encodes a *B. anthracis* protective antigen (PA) protein or a fragment thereof that encodes amino acid 204 to 764 of SEQ ID NO: 4, said second polynucleotide being operably linked to a promoter that drives expression of said PA protein or fragment thereof in cells of a mammalian subject wherein said LF protein or fragment thereof lacks metalloproteinase activity.

The prior art fails to teach such composition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

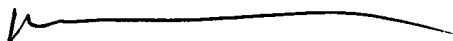
***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shannan-Shah whose telephone number is (703) 308-

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8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645  
December 28, 2003



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER